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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,424	01/14/2002	Alain Constancis	8-1032-169	5434

7590

09/05/2003

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 09/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,424

Applicant(s)

CONSTANCIS ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-24, 26-30, 32 and 39-43 is/are allowed.
- 6) ☒ Claim(s) 33-38 and 44-49 is/are rejected.
- 7) ☒ Claim(s) 25 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. The abstract of the disclosure is objected to because of the occurrence of legal phraseology “said” and “means”. Correction is required. See MPEP § 608.01(b).
2. The disclosure is objected to because of the following informalities: At page 10, line 18, “alicyclics” is misspelled. At page 10, line 33, one of the two occurrences of “nature” should be deleted. Appropriate correction is required.
3. Claims 33-38 and 44-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 33-38 are indefinite because they are dependent upon canceled claim 1. Claims 44-47 are indefinite because of the occurrence of numerous “preferably...” and “for example...” phrases. It is not clear if the scopes of the claims are to be limited to the preferred or exemplified embodiments, or if the scopes of the claims are to be limited only by the broader and generic claim language. For example, with respect to claim 44, lines 4-5, it is not clear if the claim embraces all types of solutions, or if the claim is to be limited to aqueous solutions. It is suggested that the “preferably...” and the “for example...” phrases could be deleted and made the subject matter of further dependent claims.
4. Claims 25, 31, and 44 are objected to because of the following informalities: Claim 25 does not end with a period. Claims 31 and 44 end with semicolons rather than with periods. At claim 44, line 10, “bring” should be changed to ‘bringing’ and the comma should be deleted. Appropriate correction is required.
5. Claims 33-38 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to other claims in the alternative only. Note that claims 33-

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38 are dependent upon claim 22 and upon claim 1. See MPEP § 608.01(n), especially the example in section (I)(B)(3).

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. *In re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976); *In re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

7. Claim 46 is rejected under 35 U.S.C. 103 as being obvious over Gagnieu (U.S. Patent No. 5,412,076) in view of Keusch et al (U.S. Patent No. 5,354,790) or Stemberger (U.S. Patent No. 4,407,787). Gagnieu teaches preparing an aqueous solution of succinylated cysteamine collagen under an inert atmosphere for use as an adhesive, a biomaterial for prostheses, an implant, or

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other medical articles (see, e.g., the Abstract; column 11, lines 16-27; and column 18, lines 21-23), but does not teach sterile packaging the solution. Keusch et al teach that for adhesives to be used as bandages or for skin contacting, sterile packaging is necessary (see, e.g., column 12, lines 26-30). Stemberger teaches that sterile packaging of compositions comprised of collagen which are to be used as dressings (see, e.g., column 4, lines 20-22). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to package the collagen solutions of Gagnieu under sterile conditions because packaging permits the collagen solutions to be stored for later use, and because Keusch et al and Stemberger teach that sterility is necessary for the medical uses contemplated by Gagnieu.

8. Claims 22-24, 26-30, 32, 39-43 are allowed. Claims 25 and 31 would be allowable if rewritten or amended to overcome the claim objections set forth in this Office action. Claims 33-38, 44, 45, and 47-49 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, and the claim objections set forth in this Office action.

With respect to instant claims 22-45, the prior art of record does not teach or suggest grafting thiol functions exclusively onto the aspartic and glutamic acid sidechains of collagenic chains. Gagnieu (U.S. Patent No. 5,412,076) has been carefully considered but is not deemed to teach or suggest the instant claimed invention. Gagnieu intentionally modifies non-aspartic and glutamic acid residues in collagen with spacer compounds such as carboxylated hydrocarbons so that carboxylic acid groups are present at the sidechains of amino acids where the carboxylic acid groups are not naturally present. Thus, when Gagnieu reacts the cysteic residues with the modified collagen, not only do the cysteic residues react with the sidechains of aspartic and

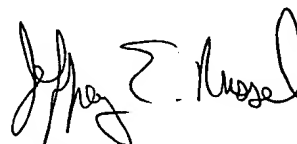
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glutamic acid residues (see, e.g., column 5, lines 31-33), the cysteic acid residues also react with non-aspartic and glutamic acid residues which have been modified with the spacer compounds (see, e.g., column 5, lines 28-31). Accordingly, Gagnieu does not teach or suggest reacting the cysteic acid residues "exclusively" with the sidechains of aspartic and glutamic acid residues present in collagen.

With respect to instant claims 47-49, the prior art of record does not teach or suggest the step of filtering a solution comprising a crosslinkable precursor of modified collagenic peptide so as to remove elements which are greater than or equal to 0.8 μm in size. The claimed size limitation is not taught or suggested by Gagnieu.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Technology Center 1600 for formal communications is (703) 872-9306; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1600 receptionist is (703) 308-0196.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
September 4, 2003